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510(k) SUMMARY
INVACARE CORPORATION'S
510(k) PREMARKET NOTIFICATION
MODEL CGR TILT SEATING SYSTEM FOR POWER WHEELCHAIRS

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

Invacare Corporation
One Invacare Way
Elyria, Ohio 44036
Phone: (440) 329-6595
Facsimile: (440) 365-4558

Contact Person: Edward A. Kroll
Director, TQM and Regulatory Affairs

Date Prepared: June 12, 2000

Name of Device and Name/Address of Sponsor:

Model CGR Tilt Seating System for Powered Wheelchairs
Invacare Corporation
One Invacare Way
Elyria, Ohio 44036
Phone: (440) 329-6595
Facsimile: (440) 365-5584

Common or Usual Name
Power Wheelchair

Classification Name
Wheelchair, Powered

Predicate Devices
Products which are substantially equivalent to the Model CGS are the Invacare Model 2G Tilt/Recline (K991119, August 19, 1999) and the LaBac Adjustable Sliding Back Power Recline System (K923363, March 24, 1993).

Intended Use
Its intended function and use is to provide pressure relief to persons confined to a powered wheelchair by providing a method of tilting the seat back.

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Technological Characteristics and Substantial Equivalence

A. Device Description

The Invacare Model CGS Power Tilt Seating System for Power Wheelchairs is a battery powered, motorized seating system designed for use with Invacare Storm power wheelchairs. Its intended function and use is to provide added comfort to persons that may be confined to a wheelchair, by providing a method of tilting the seat back.

The CGS Tilt System basically consists of an upper and lower frame assembly, a wheelchair seat and back, a drive motor/actuator mechanism and switch actuator. The lower assembly is constructed of welded steel and is mounted on linear bearing slides on both the left and right hand sides of the frame. The linear slides are mounted directly to the wheelchair frame using standard mounting screws. The lower frame assembly includes the linear drive motor/actuator assembly.

The upper frame assembly includes the wheelchair seat and back, and mounts to the lower assembly by way of mechanical linkage arms. It is also constructed of welded steel. The seat upholstery is fabricated from polyester, nylon fabric. The material meets CAL TB 117 standards for flame retardency.

The seating system includes a toggle type switch actuator for engaging the tilting motion of the seat. The toggle switch is external to housing that is easily mounted to the left or right armrest of the wheelchair, depending upon user preference. Moving the switch forward or away from the user, engages forward motion. Conversely, moving the switch backwards or toward the user engages reverse motion.

B. Substantial Equivalence

Products which are substantially equivalent to the Invacare Model CGS are the Invacare Model 2G Tilt/Recline (K991119, August 19, 1999) and the LaBac Adjustable Sliding Back Power Recline System (K923363, March 24, 1993).

PERFORMANCE DATA

The Invacare Model CGS Tilt Seating System for Power Wheelchairs meets the applicable requirements specified in the Rehabilitation Engineering Society of North America (RESNA) Standard ANSI/RESNA WC/14 (1991) and ISO Standard ISO 7176: 1993 (E) "ISO Standard, Wheelchairs - Requirements and Test Methods for the Power and Control Systems of Electric Wheelchairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 4 2000

Mr. Edward A. Kroll
Director, TQM and Regulatory Affairs
Invacare Corporation
One Invacare Way
P.O. Box 4028
Elyria, Ohio 44036-2125

Re: K001777
Trade Name: Model CGS (Center of Gravity Shift) Power Tilt System for Power Wheelchairs
Regulatory Class: II
Product Code: ITI
Dated: June 12, 2000
Received: June 13, 2000

Dear Mr. Kroll:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Lochner

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): ~~TBD~~ K001777

Device Name: *Model CGS (Center of Gravity Shift) Power Tilt Seating System for Power Wheelchairs*

Indications For Use: *Its intended function and use is to provide pressure relief to persons confined to a powered wheelchair by providing a method of tilting the seat back.*

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diane R. Vochnes

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001777

Prescription Use ___ **OR** **Over-The-Counter Use** X
(Per 21 CFR 801.109)

(Optional Format 1-2-96)